
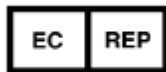


EU DECLARATION OF CONFORMITY

Product Name(s) / Trade Name(s)	iScan™Dx
Intended Purpose	The iScanDx Instrument is an In vitro diagnostic (IVD) device intended to be used by trained personnel in a professional laboratory environment for automated and quantitative detection of fluorescent signal intensities from Illumina Infinium BeadChips (bead-based microarrays) containing nucleic acid probes for human genomic variants. The resulting fluorescent intensity signals are intended for use with user-defined IVD applications.
	20081314
Basic UDI-DI (BUDI-DI)	0081627002iScan89



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5626 DK Eindhoven
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We, Illumina, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above-mentioned product(s) meet(s) the provisions of the following Regulation(s)/Directives:

Regulation EU 2017/746 on In vitro Diagnostic Medical Devices

Radio Equipment Directive 2014/53/EU

RoHS Directive 2011/65/EU as amended by (EU) 2015/863 – Annex III exemptions apply

RISK CLASS:

A B C D

CONFORMITY ROUTE:

Annex I & II+III of Regulation EU 2017/746; Self-Declaration

Common Specification (CS): N/A

Joe McMullen

Electronically signed by: Joe McMullen
Reason: Approver
Date: Jul 19, 2024 08:28 PDT

19-Jul-2024

E. Joseph McMullen
Sr. Director, Regulatory Affairs
Illumina, Inc.

Date

San Diego, California, USA
Issued in







200044750_ iScanDx Declaration of Conformity IVDR_Final

Final Audit Report

2024-07-19

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